

Appl. No. : 09/916,711
Filed : July 27, 2001

REMARKS

Claims 1-10, 12-15, and 21-33 are pending in this application. Claims 11 and 16-20 have been cancelled without prejudice as drawn to nonelected subject matter. Claim 2 has been amended. Support for the amendments is found in the specification and claims as filed.

Information Disclosure Statement

Copies of selected non-patent references cited in the IDS of January 25, 2002 are enclosed. Certain of the cited references are missing from our files. These references have been ordered and will be forwarded to you when available.

Election of Species

The application is asserted to contain claims directed to the following patentably distinct species: Species I, drawn to Figure 2a; Species II, drawn to Figure 2b; Species III, drawn to Figure 2c; Species IV, drawn to Figure 2d; Species V, drawn to Figure 2e; and Species VI, drawn to Figure 2f. Applicant elects Species I for prosecution, without prejudice. Claims 1-10, 12-15, and 21-33 are readable on Species I.

Objection to the Specification

The specification has been amended to include the missing serial number on page 22.

Claim Rejections - 35 U.S.C. § 112, second paragraph

Claims 1-4 have been rejected under 35 U.S.C. §112, second paragraph. Claim 2 has been amended to recite a body suitable for implantation in a host. In view of the foregoing amendment, Applicants respectfully request withdrawal of the rejection of Claims 1-4.

Claim Rejection - 35 U.S.C. § 103(a) - Shults et al. in view of Kawaguri et al.

Claims 1, 2, 5-10, 12-15, and 22-33 have been rejected under 35 U.S.C. §103(a) as obvious over U.S. 6,001,067 ("Shults et al.") in view of U.S. 5,171,689 ("Kawaguri et al."). Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so

found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). However, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Shults et al. disclose an implantable enzyme-based glucose monitoring device that utilizes a three electrode system including working, reference, and counter electrodes (col. 9, lines 65-67). Kawaguri et al. disclose sensor devices which include two electrode and three electrode systems, but which are not suitable for implantation.

Figs. 4, 8, and 9 of Kawaguri et al. depict three electrode systems, including working, reference, and counter electrodes, wherein the surface area of the counter electrode is less than or equal to the surface area of the working electrode. Specifically, Fig. 8 of Kawaguri et al. depicts a three electrode system wherein the working electrode has a larger working electrode surface area than the counter electrode. Fig. 7 of Kawaguri et al. depicts a two electrode system, including a working and counter electrode. As is appreciated by one skilled in the art, the "counter electrode" (as referred to by Kawaguri et al.) of a two electrode system must perform the function of both the counter and reference electrodes of a three electrode system. Namely, in contrast to a three electrode system wherein the functions of the reference and counter electrodes are provided by separate electrodes, a two electrode system includes only one electrode ("the counter") to provide the functions of both the reference and counter electrodes, incurring high demands on the electrode and resulting in instability and failure of the electrode over time. Kawaguri et al. address this instability by increasing the area of the counter electrode (e.g., to more than two times that of the working electrode) in order to stabilize the potential (col. 4, lines 18-21). However, Kawaguri et al. state that the reproducibility of the resulting two electrode system was "slightly poorer than in Example 1" (col. 4, lines 26-28). It is noted that Example 1 of Kawaguri et al. teaches a three electrode system wherein the working, counter, and reference electrode have equal surface areas (col. 3, lines 7-52).

The Office Action asserts that it would have been obvious to modify the Shults et al. sensor to use an arrangement of working and counter electrodes such as is taught by Kawaguri et

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al. to stabilize the potential of the electrodes. However, none of the three electrode systems taught by Kawaguri et al. teach or suggest that it would be desirable to have a counter electrode with greater surface area than that of the working electrode. In contrast, Kawaguri et al. disclose that a larger working electrode configuration produced very good reproducibility (e.g., a system as depicted in Fig. 8). Additionally, a modification of the three electrode system of Shults et al. to a two electrode system, such as is taught by Kawaguri (Fig. 7), would render the Shults et al. electrode system unsatisfactory for its intended purpose due to decreased reproducibility and numerous disadvantages of a two electrode system versus a three electrode system as is appreciated by one skilled in the art.

A *prima facie* case of obviousness therefore cannot be made, and Applicants respectfully request withdrawal of the rejection.

Claim Rejection - 35 U.S.C. § 103(a) - Schulman et al. in view of Kawaguri et al.

Claims 1-5, 7, 10, 12, 13, and 25-33 have been rejected under 35 U.S.C. §103(a) as obvious over U.S. 6,119,028 ("Schulman et al.") in view of Kawaguri et al.

Schulman et al. disclose an implantable enzyme-based glucose monitoring device that utilizes a four electrode system including two working electrodes, a reference electrode, and counter electrode (col. 6, line 67 through col. 7, line 2). As discussed above, Kawaguri et al. disclose sensor devices which include two electrode and three electrode systems, but which are not suitable for implantation. Kawaguri et al. do not teach or suggest increasing the counter electrode surface area in either a three electrode or four electrode system. Additionally, for the same reasons discussed above, a modification of the four electrode system of Schulman et al. to a two electrode system, such as is taught by Kawaguri et al. (see Fig. 7), would render the Schulman et al. electrode system unsatisfactory for its intended purpose due to decreased reproducibility and numerous disadvantages of a two electrode system versus a four electrode system as is appreciated by one skilled in the art.

A *prima facie* case of obviousness therefore cannot be made, and Applicants respectfully request withdrawal of the rejection.

Claim Rejection - 35 U.S.C. § 103(a) - Schulman et al. in view of Kawaguri et al.

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Claim 21 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Schulman et al. in view of Kawaguri et al. and U.S. 6,119,028 ("Ward et al."). As discussed above, the Shulman et al. sensor is unsatisfactory for its intended use if modified according to the teachings of Kawaguri et al. The teachings of Ward et al. do not address the deficiencies discussed above. Accordingly, Applicants respectfully request withdrawal of the rejection.

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

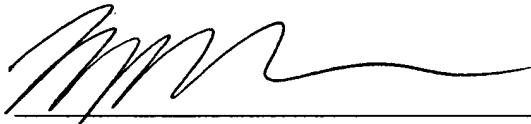
Respectfully submitted,

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Dated:

Nov. 21, 2003

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